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February 27, 2025

VIA ECF

Honorable Renée Marie Bumb
United States District Court
Mitchell H. Cohen Building and
U.S. Courthouse
Courtroom 3D
4th and Cooper Streets
Camden, New Jersey 0810

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower,
Suite 1800
Philadelphia, Pennsylvania 19103

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Chief Judge Bumb and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of the March 3, 2025 case management conference.

1. **Status of efforts to reach a stipulation on ZHP certificates of analysis and material safety data sheets.**

Plaintiffs have engaged in a lengthy meet and confer process with ZHP on this issue. As reported to the Court during this process, the Parties made progress as the discussions went forward and Plaintiffs were optimistic that a reasonable stipulation

could be reached. Unfortunately, in the past two weeks, ZHP's position hardened and from Plaintiffs' perspective the talks went backward.

The core issue is the failure by ZHP to produce fundamental, core liability documents in discovery that should have been willingly produced from the very outset of the litigation in 2019. The Certificates of Analysis are documents that were provided to ZHP by the suppliers of the chemicals/solvents purchased by ZHP for use in ZHP's new valsartan manufacturing processes—in particular for the solvents DMF, TEA, and TEA HCL. The material safety data sheets would similarly have been provided by the chemical suppliers, warning ZHP of potential risks of those substances and their contents. Based on Plaintiffs' research, it is Plaintiffs' understanding that these documents would have disclosed the risk that the solvents would contain or degrade to form the impurities dimethylamine and diethylamine, which combined with the nitrous acid already in the processes, to form NDMA and NDEA. For example, Plaintiffs located certificates of analysis from the same chemical suppliers, during the period of time when the new processes were being developed, stating that these impurities were identified in the solvents. (See attached Exhibits 1-2). These documents were utilized by Plaintiffs during the deposition of ZHP's expert, Fengtian Xue.

Plaintiffs have pressed for production of these documents, which fall squarely within the requests for production. ZHP had previously advised that they were not produced because they were paper documents and production would have been burdensome. Of course, this was not a legitimate basis for non-production. ZHP then asserted that it had searched and identified some of the documents, but none pre-dating 2016. This is significant since the processes using these substances were developed beginning at least as of 2011, and that is when the initial risk assessments were conducted regarding the new processes. ZHP produced a cherry-picked sample of these documents dated from 2016 forward, and asked Plaintiffs to accept them as full production. Plaintiffs proposed a stipulation confirming ZHP's receipt of these documents alerting them to the potential for the impurities to be present in the supplied solvents, or for the solvents to degrade and form the impurities, in return for not filing a motion for sanctions focused on the significant discovery violations (another in a line of significant violations). The discussions proceeded such that Plaintiffs thought that agreement could be reached, and then in the past two weeks that progress was reversed.

Plaintiffs now request a briefing schedule to present their motion for sanctions, which will be built upon the multiple significant discovery violations already found by the Court. The prejudice and materiality of ZHP's misconduct is

patent. The fact that Plaintiffs were forced to conduct all depositions, produce expert reports, engage in *Daubert* and dispositive motion practice, and prepare up to the one-yard line for two successive trials without these documents is so fundamentally prejudicial that Plaintiffs will be requesting significant sanctions. The most significant level of sanctions is well warranted here, where ZHP has demonstrated disdain for its discovery obligations over and over and has already been sanctioned multiple times in multiple ways.

Plaintiffs propose that their initial brief be due on or before March 14, Defendants' response on March 28, and Plaintiffs' reply on April 4. If Plaintiffs serve their initial brief prior to March 14, it is requested that the other dates be accordingly adjusted to provide ZHP 14 days to respond, and Plaintiffs 7 days to reply.

2. Status of efforts to reach stipulation on Roberts contamination levels.

The Parties have engaged in a productive meet and confer on this issue to date. Days ago, Plaintiffs served a spreadsheet containing the bottom line weighted average NDMA contamination levels for each prescription fill at issue, based on the data exchanged and discussed. Plaintiffs have asked ZHP to stipulate to the accuracy of the calculations, or to point out any issues seen and to meet and confer to resolve such issues—which amount to mathematical calculations at this point. The

alternative would be a 30(b)(6) deposition of a corporate representative to have ZHP confirm the numbers—which is obviously far less efficient. Plaintiffs need this information to finalize their specific causation expert reports. Plaintiffs request that ZHP be directed to meet and confer to finalize agreement on the calculations so this objective factual data can be agreed to for the benefit of the Parties and the Court, to maximize efficiency at the time of trial. Looking forward, Plaintiffs will be initiating similar processes with the Defendants for all bellwether trials, so the successful and efficient conclusion to this process can serve as a model.

3. Status of efforts to reach stipulation regarding CEMAT/Jinsheng Lin custodial file destruction.

The Court is well aware of the issue of the scant production on behalf of Jinsheng Lin, with almost no documents dated prior to 2018, including the absence of his July 27, 2017 email from his custodial production. During the briefing and argument on the question of whether and under what circumstances he would be deposed, ZHP asserted that his custodial file contents had been destroyed pursuant to a protocol governing the CEMAT division of ZHP where Dr. Lin was employed (CEMAT is the ZHP division responsible for analyzing and determining the root cause of impurities found in drug substances manufactured by ZHP). Plaintiffs

requested production of those alleged protocols, and ZHP then admitted that no such protocol existed.

Plaintiffs have served a proposed stipulation on ZHP on February 27, 2025. Plaintiffs await ZHP's response.

4. Parties' February 14, 2025 Letters to Court re: Wave 2 Trial Proposal.

The Parties have submitted competing letters regarding Wave 2 and will be prepared to address this issue with the Court.

5. Product ID Deficiencies.

Plaintiffs have previously confirmed their agreement to instituting a process in conjunction with the PFS deficiency process. However, Plaintiffs believe that the Parties should be required to meet and confer for a reasonable period of time, allowing at least 30 days for Plaintiffs to respond to an alleged product ID issue, and attempt to avoid the need for such issues to be submitted to the Court. This is what the Parties have been doing informally to this point.

6. PFS Deficiencies.

Plaintiffs will be prepared to address this topic during the CMC; however, Plaintiffs reiterate that the PFS deficiency process should not be used to litigate substantive legal issues. For example, in *Jerry Anderson v. Aurobindo Pharma, Ltd.*, et al., 23-cv-13680, Aurobindo seeks dismissal of the case on the grounds that

Georgia law does not permit children of the decedent to bring claims beyond wrongful death where no estate has been opened and no personal representative appointed. While Aurobindo acknowledges the wrongful death claim in the *Anderson* case is properly before the Court, it argues for dismissal of the entire case. Putting aside the merits of this assertion, which Plaintiffs dispute, and that such as issue can be addressed with a simple amendment to the short form complaint if truly a concern, the PFS process is limited to providing disclosure of information, and is not intended to be a conduit for dispositive motion practice disguised as a PFS issue. This (and any other) substantive issue does not belong in the PFS deficiency process. It should be addressed if and when the *Anderson* case is selected for trial and motion practice, at which point the parties can fully brief the matter. This tactic should be explicitly prohibited moving forward.

Respectfully,

ADAM M. SLATER

Encls.

Cc: All counsel of record (via ECF)